REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 12, 13, 15-26, 38-35, 37, 39 and 40-68 are now pending, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Thus, the withdrawn claims are cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents; and, claims 18, 20-26 and 39 are amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, so as to not depend upon a withdrawn claim. The cancellation and amendment of claims is to advance prosecution and place the application in condition for early allowance.

Support for claims 40-68 can be found throughout the application as originally filed, including in the original claims and the presently pending claims. More specifically, based on the term "adjuvant" in the claims prior to this paper, and the method claim prior to this paper, claims 40 and 41 and the claims dependent thereon parallel claims 12, 13, 15-26, 38-35, 37, and 39, and are directed to methods for enhancing the immunogenicity of a polypeptide encoded by open reading frame (ORF) 1 of porcine circovirus type II (PCV-2), ORF2 of PCV-2, ORF1 of porcine circovirus type I (PCV-1) or ORF2 of PCV-1 expressed *in vivo* in a porcine host by at least one plasmid that encodes and expresses *in vivo* in a porcine host the polypeptide. No new matter is added by claims 40-68; and, claims 40-68 do not represent a separate invention from claims 12, 13, 15-26, 38-35, 37, 39 as these lattermost mentioned, and previously-pending, claims employ the term "adjuvant" and an "adjuvant" enhances immunogenicity. Thus, claims 40-68 should be entered in this application and searched and examined with claims 12, 13, 15-26, 38-35, 37, 39.

Any fee occasioned by the new claims herein or any overpayment in such a fee, may be charged or credited to Deposit Account No. 50-0320.

It is submitted that the claims as originally-presented and as herein presented are patentably distinct from the references cited by the Examiner, and that these claims – the claims

herewith and the claims originally-presented - are and were in full compliance with the requirements of 35 U.S.C. §112. The addition of claims herein is not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the addition of claims herein is made simply for clarification and to round out the scope of protection to which Applicants are entitled.

It is explicitly submitted that the amendment, cancellation and addition of claims herein is not a narrowing of scope from the originally-presented claims, such that there should be no estoppel by the amendments herewith.

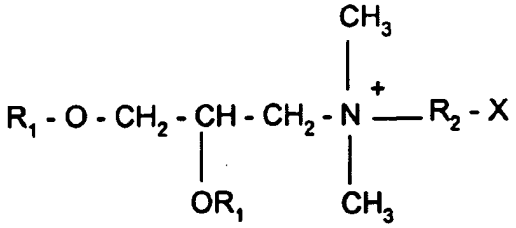
II. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 12, 18-26, 36 and 39 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Poet et al., U.S. Patent No. 6,217,883, as evidenced by Meehan et al. (J. Gen. Virol. 1998, 79:2171-79), in view of Eppstein et al., U.S. Patent No. 4,946,787. Claims 13, 18-26, 37 and 39 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Poet et al., in view of Neurath et al., U.S. Patent No. 6,165,493. And, claims 12, 15-26, 28-35, 37 and 39 were rejected as allegedly unpatentable over Poet in view of Eppstein in further view of Nabel et al., U.S. Patent No. 5,910,488. These rejections shall be addressed collectively.

Eppstein, either individually or in any combination, fails to teach or suggest the instant invention; and thus, fails to supply the deficiencies of Poet, Meehan and Nabel.

More specifically, the adjuvant compounds of the formula of claims 12 and 40 and the claims dependent thereon are not taught or suggested by Eppstein.

In claims 12 and 40 and the claims dependent thereon, the formula is:



Note specifically that in the formula of claims 12 and 40 and the claims dependent thereon, X is part of the molecule (i.e., note the bond linking R_2 and X); and, that X is a hydroxyl or amine group.

In contrast, in Eppstein's formula, X is **NOT** bonded to R^4 and is **NOT** a hydroxyl or amine group that is part of the molecule; but rather, "X" in Eppstein's formula is an anion, e.g., a

halide anion, an organic acid-derived anion (*see, e.g.*,col. 8 of Eppstein). Furthermore, Eppstein's R^4 is not equivalent to X or R_2-X in the formula of claims 12 and 40 and the claims dependent thereon because Eppstein's R^4 is H, C_{1-8} alkyl or an aryl or aralkyl having 6-11 carbon atoms.

Accordingly, it is respectfully submitted that the Office Action, at page 6, mischaracterizes Eppstein: **Eppstein does not teach a formula that embraces the formula of claim 12 of the instant application.**

Further still, Eppstein does not teach or suggest the use of a lipid as an adjuvant, i.e., complexed to a DNA plasmid to enhance immunogenicity, as set forth in the instant claims.

Therefore, the present invention is not obvious, and Poet et al., U.S. Patent No. 6,217,883, as evidenced by Meehan et al. (J. Gen. Virol. 1998, 79:2171-79), in view of Eppstein et al., U.S. Patent No. 4,946,787, fails to teach or suggest the instant invention; and, it is respectfully requested that the Section 103 rejection based on Poet, Meehan and Eppstein be reconsidered and withdrawn.

As to Neurath, the portion cited – Col. 28 – appears to relate to a **topical** formulation containing an organic anti-HIV or anti-Herpesvirus or anti-bacterial compound, namely cellulose acetate phthalate (CAP) or hydroxypropyl methylcellulose phthalate (HPMCP), and carbomer (*inter alia*).

There is no teaching or suggestion in the cited portion of Neurath of any viral particles in the Neurath composition.

There is no teaching or suggestion in the cited portion of Neurath of any immunogenic compositions containing carbomer.

There is no teaching or suggestion in the cited portion of Neurath: of carbomer as an adjuvant, and particularly as an adjuvant for a plasmid composition, or of carbomer enhancing the immunogenicity of a plasmid composition.

Thus, it is respectfully submitted that the characterization of Neurath at page 7 of the Office Actin is incorrect.

Therefore, the rejection under Section 103 based on Poet in view of Neurath, it is respectfully submitted, is incorrect, as the characterization of Neurath in the Office Action appears to be incorrect. Accordingly, reconsideration and withdrawal of the Section 103 rejection based on Poet in view of Neurath is respectfully requested.

In view of the foregoing, it is also clear that the rejection based on Poet and Eppstein in view of Nabel must also fail, because, as discussed above, Eppstein, either individually or in any combination, does not teach or suggest the formula of claims 12 and 40 or the use of compounds of that formula in a complex with DNA plasmids as an adjuvant, *inter alia*.

Nabel involves the use of lipids to form liposomes (which necessitates specific methods involving the use of chloroform and evaporations; *see, e.g.,* Nabel, Example 10).

The present invention involves lipids that are complexed with DNA plasmids, for adjuvanting activity, e.g., the use of lipids that are complexed with DNA plasmids to enhance immunogenicity; and, this too is not taught or suggested in Nabel or any of the other cited documents.

Accordingly, Nabel, either individually or in any combination, fails to teach or suggest the instant invention.

And, reconsideration and withdrawal of the Section 103 rejection based on Poet and Eppstein in view of Nabel is respectfully requested.

Consequently, in view of the remarks herewith, reconsideration and withdrawal of the obviousness rejections under Section 103 are warranted and such action is respectfully requested.

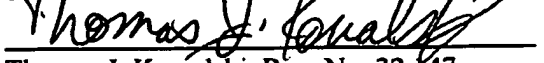
REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to any paper issuing other than a Notice of Allowance, an interview is respectfully requested; and, the Examiner is further respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for the interview.

CONCLUSION

In view of the amendments and remarks herewith, the application is in condition for allowance. Early and favorable reconsideration of the application, reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, or an interview at an early date, are earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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Appendix: Marked-Up Version To Show Changes Made

IN THE CLAIMS

Please amend the claims, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

18. (Amended) The immunogenic preparation according to any one of claims 12, 13, [14,] 15, 16 or 17 further comprising a porcine cytokine or a plasmid that encodes and expresses a porcine cytokine.

20. (Amended) The immunogenic preparation according to claim 12[,] or 13, [or 14,] further comprising a plasmid encoding and expressing an immunogen from a porcine pathogenic agent other than PCV-2 or PCV-1.

21. (Amended) The immunogenic preparation according to any one of claims 12, 13, [14,] 15, or 16, wherein the preparation includes at least one plasmid that contains and expresses ORF1 of PCV-2.

22. (Amended) The immunogenic preparation according to any one of claims 12, 13, [14,] 15, or 16, wherein the preparation includes at least one plasmid that contains and expresses ORF2 of PCV-2.

23. (Amended) The immunogenic preparation according to any one of claims 12, 13, [14,] 15, or 16, wherein the preparation includes at least one plasmid that contains and expresses ORF1 and ORF2 of PCV-2.

24. (Amended) The immunogenic preparation according to any one of claims 12, 13, [14,] 15, or 16, wherein the preparation includes at least one plasmid that contains and expresses ORF1 of PCV-2 and ORF2 of PCV-2.

25. (Amended) The immunogenic preparation according to any one of claims 12, 13, [14,] 15, or 16, wherein the preparation includes at least one plasmid that contains and expresses ORF1 of PCV-1.

26. (Amended) The immunogenic preparation according to any one of claims 12, 13, [14,] 15, or 16, wherein the preparation includes at least one plasmid that contains and expresses ORF2 of PCV-1.

39. (Amended) A method for eliciting an immunogenic response in a porcine host against porcine circovirus comprising administering to the porcine host the immunogenic preparation of any one of claim 12, 13, [14,] 15 or 16.